

Food and Drug Administration, HHS

§ 165.3

suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) The peanut ingredients referred to in paragraph (a) of this section are:

(1) Blanched peanuts, in which the germ may or may not be included.

(2) Unblanched peanuts, including the skins and germ.

(c) The seasoning and stabilizing ingredients referred to in paragraph (a) of this section are suitable substances which are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act), or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Seasoning and stabilizing ingredients that perform a useful function are regarded as suitable, except that artificial flavorings, artificial sweeteners, chemical preservatives, and color additives are not suitable ingredients in peanut butter. Oil products used as optional stabilizing ingredients shall be hydrogenated vegetable oils. For the purposes of this section, hydrogenated vegetable oil shall be considered to include partially hydrogenated vegetable oil.

(d) If peanut butter is prepared from unblanched peanuts as specified in paragraph (b)(2) of this section, the name shall show that fact by some such statement as "prepared from unblanched peanuts (skins left on)." Such statement shall appear prominently and conspicuously and shall be in type of the same style and not less than half of the point size of that used for the words "peanut butter." This statement shall immediately precede or follow the words "peanut butter," without intervening written, printed, or graphic matter.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the

applicable sections of parts 101 and 130 of this chapter.

[42 FR 14475, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2886, Jan. 6, 1993; 61 FR 9325, Mar. 8, 1996; 63 FR 14035, Mar. 24, 1998]

PART 165—BEVERAGES

Subpart A—General Provisions

Sec.

165.3 Definitions.

Subpart B—Requirements for Specific Standardized Beverages

165.110 Bottled water.

AUTHORITY: 21 U.S.C. 321, 341, 343, 343-1, 348, 349, 371, 379e.

SOURCE: 60 FR 57124, Nov. 13, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 165.3 Definitions.

(a) *A lot* is:

(1) For purposes of determining quality factors related to manufacture, processing, or packing, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible and usually designated by a common container code or marking, or in the absence of any common container code or marking, a day's production.

(2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.

(b) A *sample* consists of 10 subsamples (consumer units), one taken from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific standard in this part.

(c) An *analytical unit* is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.